Technical Data Sheet

Cosmopor® I.V. transparent, cannulae fixation, sterile

General Product Description / Intended Purpose

Cosmopor®I.V. transparent are non-active, single-use, self-adhesive, sterile devices consisting of a coated backing material laminate with a fenestration (covered with PU-film, to allow the observation of the cannulae/catheters during the application of the dressing) and an I.V. opening for the cannula insertion, protected with silicone paper, and including self-adhesive fixation strips attached to the silicone paper, for the sterile covering and fixation of cannulae/catheters.

The products are intended for humans, without restrictions (in age group, weight range, health status or condition), for use by healthcare professionals, in contact with intact skin (healthy skin) and breached skin, and long-term (Duration > 30 days, acc. to MDR and ISO 10993-1:2018) duration of use.

The products do not contain resorbable components, medicinal products / drug substances (derived from human blood or plasma or not), tissues or cells of human or animal origin, radioactive substances, nanomaterials or other hazardous components.

The dressings are sealed individualy in peel-pouches and packed in cardboard folding boxes.

Application / Indication

Sterile covering and fixation of cannulae/catheters.

Unpackaging, handling, application and disposal of the dressing must be performed with sterile gloves. Clean and disinfect the application area thoroughly and ensure that the skin is dry. Use of skin creams, ointments or lotions may impair adhesion of the dressing.

1. Remove the fixation strips from the protective cover number 1 and use them to fixate the catheter, cannula wings, cannula needle and/or tubes. The removal and application of the fixation strips can also be performed after the complete application of Cosmopor ® I.V. transparent to further fixate the cannula/cannula wings and the dressing itself (please see step 4). If that is the case, do not dispose of the protective cover number 1 until removal and application of the fixation strips.
2. After removing the protective cover number 1, apply the dressing with the transparent window centered on the cannula insertion/exit site. Please note that in the case of Cosmopor ®I.V. transparent 12x10cm, the upper side of protective cover number 3 maybe used as an additional gripping point to precisely position the dressing.
3. Release protective cover number 2 from the dressing.s legs and apply them onto the catheter, cannula and/or cannula wings. Gently press the entire dressing onto the skin, conforming it to the body contours and the cannula or catheter shape for a secure fixation.
   For Cosmopor ®I.V. transparent 12x10cm, carefully remove the remaining protective cover number 3 afterwards, then apply the upper part of the dressing onto the skin.
4. The application of the fixation strips may also be performed after step number 3 to further fixate the catheter, cannula, cannula wings and/or tubes (if applicable) and the dressing itself.

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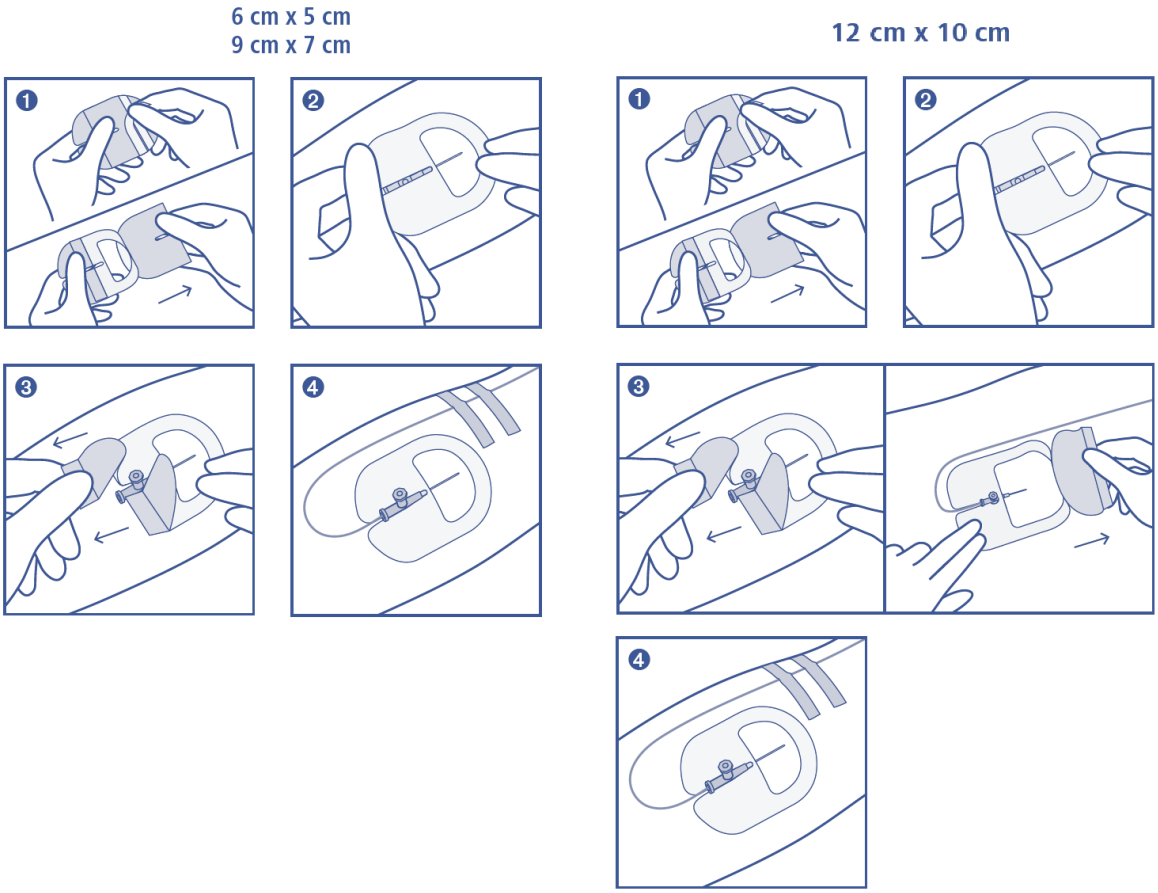

Removal

To safely remove or change Cosmopor ®I.V. transparent after its individual application time, carefully remove the fixation strips, then loosen an edge of the dressing.s legs and remove them completely. Once the legs have been removed, the cannula must be pressed carefully against the puncture site, so the cannula needle does not move. Then the rest of the dressing must be stretched and removed in its totality, avoiding the cannula's and needle's movement.

Reference Numbers

Packaging	S	M	L
Dimensions (mm)	60x50	90x70	120x100
Packaging format	P100	P100	P50
Reference number	900 817/0	900 818/0	900 819/0

Contra-Indications / Side Effects / Warnings

Dressing not indicated for absorbing exudate or covering of wounds. Adverse reactions may occur in patients who are allergic or hypersensitive to any of its components.

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Sterile Device

Prevention symbols added:

Do not use if package is damaged.

Do not resterilize.

Single Use Device

Reusing a single-use medical device is dangerous. Reprocessing devices, in order to reuse them, may seriously damage their integrity and their performance. Information available on request.

Product Disposal

In order to minimize the risk of potential infection hazards, or environmental pollution, disposable components of the medical device should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards.

Incident Reporting

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

Product Performance Characteristics

Cosmopor ® I.V. transparent			
Property	**Test method**	**Unit**	**Specification ***
Peel adhesion – Non-woven adhesion on silk (machine direction).	Evaluation of the peel test based on DIN ISO 6133:2017-04, procedure B.	N/25mm	14 ± 3
Peel adhesion - Polyurethane adhesion on PE plates.	Evaluation of the peel test based on DIN ISO, 6133:2004-05, procedure B.	N/25mm	7 ± 3
Peel adhesion - Fixation strips adhesion on silk (machine direction).	Evaluation of the peel test based on DIN ISO 6133:2017-04, procedure B.	N/25mm	13 ± 3

(*) Specification obtained through internal test results. The tests are performed periodically to ensure the product meets the specifications.

Labelling

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Lot-No. with 9-Digit Code

	Eg.:		Eg.:	
LOT	**0**	**XXX**	**03**	**XXX**
	Year	For internal purposes only	Manufacturing week	For internal purposes only

Manufacturing Date

E.g.:	**2025**	**01**	**14**
	Year	Month	Day

Use-by-Date

	Eg.:	Eg.:	
	2025	**01**	**01**
	Year	Month	Day

Shelf Life: **5 years**

Medical Device

MD

Unique Device Indetification (UDI)

UDI

Single Sterile Barrier System

Single sterile barrier system

Do not re-use

Legal Manufacturer

PAUL HARTMANN AG
Paul-Hartmann-Straße 12
89522 HEIDENHEIM, GERMANY
www.hartmann.info

Distributor

Distributor

HARTMANN USA, Inc.
Rock Hill, SC 29739, USA
1-800-243-2294
www.hartmanninfo.com

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